

CLAIMS

1. A stable pharmaceutical composition comprising a mixture of
- (i) an ibuprofen medicament;
 - 5 (ii) a domperidone medicament; and
 - (iii) a carrier material

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one release modifying agent.

- 10 2. A stable pharmaceutical composition comprising a mixture of
- (i) an ibuprofen medicament;
 - (ii) a domperidone medicament; and
 - 15 (iii) a carrier material

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one release modifying agent, excluding

20 (a) a compressed tablet comprising granulated ibuprofen and a carrier material consisting essentially of either maize starch at 35-38% total tablet weight in combination with dried maize starch at 3-4% total tablet weight or microcrystalline cellulose at 10-11% total tablet weight in combination with croscarmellose sodium at 14-16% total tablet weight and pre-gelled starch at 10% total tablet weight;

25 (b) a direct compression tablet comprising a carrier material consisting essentially of microcrystalline cellulose at 8-11% total tablet weight and lactose at 5-6% total tablet weight;

30 (c) a hard gelatin capsule comprising a carrier consisting essentially of maize starch at 15-20% total capsule contents weight in combination with pre-gelled starch at 5-6% total capsule contents weight.

3. A compressed tablet composition including an ibuprofen medicament, a domperidone medicament and a carrier material comprising a compressed mixture of

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- (a) a granular component comprising said ibuprofen medicament and at least a first portion of said carrier material; and
- (b) a powder component comprising a lubricant material and an optional further portion of said carrier material,

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said domperidone medicament being present in either of components (a) and (b), characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one disintegrating agent.

- 15 4. A composition according to any one of claims 1 to 3 characterised by comprising a granulating agent present to an extent of up to 10% of total tablet weight.

5. A composition according to any one of claims 1 to 4 comprising a
20 granulating agent consisting essentially of one or more of the following:

polymeric granulating agents selected from natural gums, synthetic gums and cellulose materials; a sugar granulating agent; a starch granulating agent.

- 25 6. A composition according to either one of claims 4 and 5 characterised in that the granulating agent is a cellulose derivative.

7. A tablet according to claim 6 characterised in that the granulating agent is hydroxypropyl cellulose or hydroxypropyl methylcellulose.

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8. A directly compressed tablet composition comprising
- (i) an ibuprofen medicament;
 - (ii) a domperidone medicament; and

(iii) a carrier material,

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one disintegrating agent and a lubricating agent.

9. A composition according to any one of the preceding claims comprising 20-60% carrier material including up to 15% of a discrete disintegrant material.

10. A composition according to any one of the preceding claims wherein the carrier material consists essentially of a diluent substantially without disintegrating properties, a diluent with disintegrating properties, a discrete disintegrant and a lubricating agent.

11. A composition according to any one of the preceding claims wherein the carrier material comprises a cellulose component, a phosphate component, a starch component or a sugar component or mixtures thereof.

12. A composition according to any one of the preceding claims wherein the carrier material consists essentially of one or more of the following diluents: microcrystalline cellulose, tricalcium phosphate and lactose.

13. A composition according to any one of the preceding claims comprising one or more discrete disintegrants including croscarmellose sodium and sodium starch glycolate.

14. A composition according to any one of the preceding claims in the form of a unit dose comprising 50-400 mg ibuprofen medicament and 5-20 mg domperidone medicament.

15. A solid composition comprising a non-compressed mixture of

- (i) an ibuprofen medicament;
- (ii) a domperidone medicament; and

(iii) a carrier material

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one release modifying agent.

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16. A liquid or semi-solid composition comprising

(i) an ibuprofen medicament:

(ii) a domperidone medicament; and

10 (iii) a carrier material

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one release modifying agent.

15 17. A composition according to any one of the preceding claims comprising either racemic ibuprofen or S(+)-ibuprofen or the sodium or lysine salts thereof, present to an extent of 50-65% by weight of the composition.

18. A composition according to any one of the preceding claims comprising
20 either domperidone or the maleate salt thereof, present to an extent of 1-5% of the
composition.

19. The use of a carrier material which is substantially free of povidone and which comprises at least one diluent combined with at least one release modifying agent in a stable pharmaceutical composition comprising an ibuprofen medicament and a domperidone medicament.

20. The use according to claim 19 wherein the release modifying agent is a disintegrating agent.

21. A process to prepare a pharmaceutical composition according to claim 1 comprising incorporating said ibuprofen medicament and said domperidone medicament with the carrier material as a homogeneous

blend and forming it into a unit dosage form.

22. A process to prepare a compressed composition according to any one of claims 1-6 comprising (a) granulating said ibuprofen medicament, optionally with
5 said domperidone medicament, with at least a first portion of said carrier material and a granulating fluid; (b) drying said granules; (c) blending with a lubricating agent and optionally a flow aid to form a homogeneous mixture, and (d) compressing into tablets.
- 10 23. A process according to claim 22 further comprising a cellulose material as a granulating agent.
24. A method of treating migraine which comprises the administration to a patient in need thereof a stable pharmaceutical composition according to any one of
15 claims 1-18.

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add A & B
add B4
add C3